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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/614,790	07/12/00	KLEYNE S	HME/7982.001

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CHERNOFF VILHAUER MCCLUNG & STENZEL LLP
1600 ODS TOWER
601 SW SECOND AVENUE
PORTLAND OR 97204-3157

EXAMINER	
WILLIS, M	
ART UNIT	PAPER NUMBER
1619	8

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/614,790	KLEYNE, SHARON F.	
	Examiner	Art Unit	
	Michael A. Willis	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-43 have been cancelled. Claims 44-74 are pending. The claims are drawn to methods for moisturizing the eye.

Request for Continued Examination

1. The Request for Continued Examination filed on 13 July 2001 under 37 CFR 1.114 is acceptable and an RCE has been established. An action on the RCE follows.

Double Patenting

2. The following sets of claims are duplicates or else are so close in content that they both cover the same thing, despite slight differences in wording: 46 and 54; 58 and 63; 64 and 66; 55 and 60; 50 and 59; 73 and 74. Applicant is advised that should any of the claims in each set of claims be found allowable, the corresponding claim in the set will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 45, 64, and 67-73 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 09/823,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods for moisturizing the eye comprising administering to the surface of the eye droplets of a fluid consisting essentially of water in the form of a mist.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 48, 53, 62, 70, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because of the range of "1 to 2 microliters" while their base claims excluded a range of 2 by stating "less than about" 2.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 44-74 are rejected under 35 USC 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518).

9. Embleton teaches the advantages of administering smaller volumes of ophthalmic solutions to the eye. The tear volume can increase to about 30 microliters before overflowing occurs and the excess fluid is lost (see page 1, lines 5-23). Embleton also teaches that ocular bioavailability is enhanced by delivery to the eye in the form of a jet or stream of droplets (see page 2). As a general guide, Embleton teaches that droplet diameters in the range of 20 to 1000 microns are suitable, and that total volume should not exceed 20 microliters (see page 3, lines 11-37). Ophthalmic treatment liquids may be aqueous, and optionally contain a therapeutic compound (see page 12, lines 6-9). Specifically named fluids include water, optionally containing polymeric compounds (see page 13, lines 7-12). It is the position of the examiner that the optional ingredients are not required in the ophthalmic treatment liquids, and that Embleton specifically teaches the use of water as an ophthalmic treatment liquid. While the reference teaches the use of droplets with diameters generally in the range of 20-1000 microns and total

volumes less than 20 microliters, the reference lacks teaching droplet diameters specifically in the 10-20 micron range and volumes in the 1-3 microliter range.

10. Laibovitz teaches a device and method for delivering small microliter volumes of liquid preparations to the eye. Laibovitz teaches that the ability of a system to deliver small volumes of a liquid as droplets is of particular interest. The size of the drop is as found in an aerosol or mist, in the 1-5 micron range (see col. 3, lines 11-27). Laibovitz teaches that the smaller volumes are especially designed to remain within the capacity of the eye to hold the solutions (see col. 3, lines 35-40). The apparatus as taught by Laibovitz delivers small volumes between 1 and 25 microliters (see col. 5, lines 8-14). Tables 1 and 2 show delivery of 2 microliters of fluid by the device as taught by Laibovitz (see col. 13, line 19 through col. 15, line 40).

11. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the administration of compositions as taught by Embleton by the use of the methods and apparatus as taught by Laibovitz in order to avoid overflowing the capacity of the tear film and subsequent loss of the administered fluid.

Response to Arguments

12. Applicant's traversal with respect to the rejection of claims 1-43 under 35 USC 102(b) and 35 USC 103(a) in a previous Office Action is acknowledged, but considered moot in view of the cancellation of said claims. Applicant's arguments filed 13 July 2001 are considered as they apply to claims 44-74.

13. Applicant argues that Embleton does not disclose treatment with an aqueous fluid that consists essentially of water as called for in claims 45, 57, and 64-74. In support of this argument, applicant cites examples of ophthalmic solutions that contain ingredients other than water. Applicant's reasoning is that because there are products on the market that contain ingredients other than water, Embleton's teaching of "water" should be understood as "solutions that are based on water".

It is the position of the examiner that Embleton specifically teaches water as an ophthalmic treatment liquid. Embleton teaches that ophthalmic treatment liquids may be aqueous, and optionally contain a therapeutic compound (see page 12, lines 6-9). The class of ophthalmic treatment liquids includes artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc. (see col. 13, lines 7-12). Specifically named fluids include water, optionally containing polymeric compounds (see page 13, lines 7-12). It is the position of the examiner that the optional ingredients are not required in the ophthalmic treatment liquids. Embleton's teaching of "water" is understood as "water" or "solutions that are based on water".

14. Applicant further argues that Embleton's teaching of a jet or stream of droplets is distinct from a mist. It is noted that page 6, line 10 of the specification defines mist as dispersed droplets in air. The examiner does not recognize a distinction between mist, multiplicity of droplets, dispersed droplets in air, stream of droplets, or a cloud-like aggregation of minute globules of water.

15. Applicant argues that Embleton discloses a droplet volume range of 3-8 microliters and does not disclose volumes between 1 and 3 microliters. Embleton

actually teaches volumes of less than 20 microliters, preferably no greater than 10 microliters, and most preferably in the range 3 to 8 microliters (see page 3, lines 30-37). The fact that the range of 1-3 microliters is not the most preferred range does not mean that 1-3 microliters is outside of Embleton's teachings. However, any deficiencies of Embleton are met by Laibovitz's teachings of delivery of 2 microliters of fluid (see col. 13, line 19 through col. 15, line 40).

16. Applicant argues that Embleton does not disclose droplets smaller than 20 microns in diameter. Embleton actually teaches "as a general guide jet/droplet diameters in the range 20 to 1000 microns are suitable in the practice of the invention." The deficiencies of Embleton are met by Laibovitz, who teaches that the ability of a system to deliver small volumes of a liquid as droplets is of particular interest. The size of the drop is as found in an aerosol or mist, in the 1-5 micron range (see col. 3, lines 11-27).

17. Applicant's arguments with respect to Rocca and Varma are moot, in view of the new grounds of rejection as stated above.

Conclusion

Applicant's arguments filed 13 July 2001 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Michael Hartley
Primary Examiner

Michael A. Willis, Ph.D.
Patent Examiner
Art Unit 1619

August 13, 2001